Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat



سلطنة عُمان وزارة الصحة المديرية العامة للصيدلة والرقابة الدوائية مسقط



To:

The Director General of Health Services in all Governorates

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies, MOH

Director General of Pvt. Health Est. (to kindly arrange distribution to all Pvt. Hospitals)

Director General of Primary Health Care, MOH

Director General of Specialised Medical Care, MOH

Director General of Quality Assurance Centre, MOH

Director General of Disease Surveillance and Control, MOH

Director of Rational Drug Use

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

All Private Pharmacies & Drug Stores

After Compliments,

Please find attached our Circular No. 227

_dated 0511212022 regarding

Nebulised asthma rescue therapy in children.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Section Head (Drug Information)





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Circular No. 227/2022

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Nebulised asthma rescue therapy in children: home use of nebulisers in paediatric asthma should be initiated and managed only by specialists

The Directorate General of Pharmaceutical Affairs & Drug Control would like to share new advice that was published by The Medicines and Healthcare products Regulatory Agency (MHRA) website to healthcare professionals and patients regarding home use of nebulised asthma rescue therapy in children.

The use of a nebuliser purchased independently of medical advice for use in the home to deliver nebulised asthma rescue medications to children can mask a deterioration in the underlying disease and may increase the risk of potentially fatal delays in seeking medical attention if asthma deteriorates. If home use of a nebuliser for the acute treatment of asthma in children under 18 years of age is considered necessary, this should be initiated and managed by an appropriate specialist. This is consistent with current clinical guidance.

Advice for healthcare professionals:

- use of nebuliser devices at home to deliver asthma rescue medication to children and adolescents, without
 adequate medical supervision, can mask a deterioration in the underlying disease, which could result in
 delays in seeking medical attention and have fatal or serious consequences
- only specialists in asthma should initiate and clinically manage use of nebulisers and associated nebulised medicines at home for acute treatment of asthma in children and adolescents
- independent purchase of nebuliser devices outside of medical advice for use at home to deliver rescue therapy for the acute treatment of asthma in children and adolescents is not recommended
- pharmacists are asked to advise people seeking to purchase a nebuliser for this purpose that such home
 use of nebulisers is not recommended without specialist clinical management.
- continue to report suspected adverse reactions to nebulised medications and adverse incidents involving nebulisers.

Advice to provide to patients or caregivers:

- seek urgent medical assistance if worsening asthma symptoms are not relieved by rescue medicines
 prescribed by a healthcare professional, even if the child has short-term recovery following use of
 prescribed nebulised medication.
- children under 18 years should only use a nebuliser to take asthma reliever medications under specific
 instructions of a doctor with expertise in asthma, so that deterioration in asthma control can be detected
 and treated without delay
- only use a nebuliser device recommended by a doctor and ask for training from your asthma nurse, pharmacist, or other healthcare professional on how it should be used and maintained and when to seek medical advice
- if your child or teenage have been using a nebuliser at home, and have not yet been referred to a specialist in asthma, talk to their physician about referral to a specialist.

Concerns over nebulisers in paediatric acute asthma

Nebulised rescue (or reliever) asthma medicines are prescription-only medicines. Clinical guidance from NICE recommends use of nebulised rescue medicines only in severe or life-threatening acute exacerbations of paediatric asthma, or, on a regular basis, only in patients with severe asthma when they are unable to use other inhalation devices. Use of a nebuliser under both of these circumstances should be strictly under medical supervision.





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Nebulised asthma medications affected by the recommendations

Medicine	Specific brands and product information	Indications from the product information
Ipratropium	Atrovent UDVs,	When used concomitantly with inhaled β2-agonists, for treatment of reversible airways obstruction as in acute and chronic asthma:
	Ipratropium Bromide Nebuliser Solution	 for acute asthma in children younger than 5 years, for acute and chronic asthma in adults and children older than 5 years
Salbutamol	Ventolin Respirator Solution,	
	Salbutamol 2mg/ml Nebuliser Solution	For use in the routine management of chronic bronchospasm unresponsive to conventional therapy, and in the treatment of acute severe asthma in adults, adolescents and children aged 4 years or older.
	Salbutamol 2.5mg/2.5ml	
	Nebuliser Solution	
Terbutaline	Bricanyl Respules,	The state of the s
	Terbutaline Nebuliser Solution	

Call for reporting

Ipratropium (atrovent) and salbutamol (ventolin) solu. for inhalations are registered drugs in Oman and terbutaline (bricanyl respules) is occasionally imported. Consumers and health care providers are encouraged to report adverse drug reactions and any drug related problems to the DGPA&DC.

Dr. Mohammed Hamdan Al Rubaie DIRECTOR GENERAL



